510(k) Summary

Device Trade Name: Stabiliz Fixation System

Manufacturer:
Stabiliz Orthopaedics, LLC
3225 Arch Street
Philadelphia, PA 19104

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Contact:
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Prepared by:
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Date Prepared: November 16, 2012

Classifications: 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories

and

21 CFR 888.3040: Smooth or threaded metallic bone fixation fasteners

Class: II

Product Codes: HRS, HWC

Indications for Use:
Stabiliz Fixation System is intended for fixation of fractures, osteotomies and nonunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

Device Description:
The Stabiliz Fixation System includes standard straight LCP plates, metal locking screws, cortical screws, and fully-threaded and partially-threaded cancellous screws in various sizes and geometries.

Predicate Devices:
Comparative information presented in the 510(k) supports the substantial equivalence of the Stabiliz Fixation System to the following predicate devices: Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684); and Zimmer® Universal Locking System (K060710).

Substantial Equivalence:
The components of the Stabiliz Fixation System are substantially equivalent to the identified predicates with respect to indications for use, geometry, available sizes, materials, methods of fixation to bone, and performance.

Preclinical Testing:
The non-clinical tests performed by the company include an analysis of strength of the Stabiliz Fixation System plates and screws relative to legally marketed plates and screws. The analyses demonstrate that the Stabiliz Fixation System is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 27, 2012

Stabiliz Orthopaedics, LLC
% Douglas L. Cerynik, M.D.
President & Chief Executive Officer
3225 Arch Street
Philadelphia, Pennsylvania 19104

Re: K120651
Trade/Device Name: Stabiliz Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 19, 2012
Received: November 19, 2012

Dear Dr. Cerynik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K120651

Device Name: Stabiliz Fixation System

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Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi
for (Division Sign-Off)
Division of Orthopedic Devices

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